

**Kaczmarek, Chris**

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**From:** Taub, Cynthia <CTaub@steptoe.com>  
**Sent:** Wednesday, May 21, 2014 9:47 AM  
**To:** 'Talbert, Stephanie (ENRD)'  
**Cc:** Allison\_Starmann@americanchemistry.com; Goldberg, Seth; Kaczmarek, Chris; Ross, Philip  
**Subject:** RE: Next meeting date  
**Attachments:** Industrial Fungicide label.redacted.pdf

Stephanie-

Thank you for this information.

With regard to the next meeting date, May 28th works for Seth and I. Allison will not be available either day next week, so we will carry on without her. How about 9-11 am or 1-3 pm? We would be happy to host the meeting at Steptoe if that works for you.

With regard to the implementation letter, what we meant by "follow-on" was provided in our term sheet as follows:

"EPA should commit to providing clear guidance as to how it will apply the new data requirements to new active ingredients, new formulated products for existing actives where the new regulation creates data gaps for the active, ***active ingredient applications for substances that already are registered (follow on active applications)***, and me-too formulated products. The guidance also should explain the timing and process through which EPA plans to impose these new requirements on existing registrations. Among the issues that should be answered by such guidance are: will EPA hold up amendments and/or other actions until new data are submitted, will EPA issue data call-ins for the new data and, if so, on what schedule, will EPA plan to impose the new requirements through registration review?" (emphasis added).

Please us know whether all of the above will be addressed in the implementation letter.

In follow up to our last meeting, attached please find a sample EPA-approved label that includes the word "fungicide" and is not for use against public health organisms. We removed the company name, product name, active ingredient, establishment number, and use rate information from the attached copy. This is just one example of many labels available on NPIRS that include "fungicide" claims on the label where the fungicide claim is not based on activity against fungi pathogenic to man or other animals.

Finally, at the last meeting, we discussed the two "principles" ACC listed in the term sheet for the USI (principles for when tolerances and non-dietary oral risk assessments would be required). We understand EPA's position is that both of these subjects are outside 158W and therefore are not within the scope of potential settlement. ACC is willing to remove these two "principles" from its list of terms, and therefore remove these issues from the settlement discussions, as long as EPA's attorneys confirm in writing, to both ACC and AD, that ACC and its members will be immediately free to discuss these two topics with AD directly. Confirmation by email will suffice.

We look forward to your response.

Cynthia

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Nonresponsive

Cynthia,

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## INDUSTRIAL FUNGICIDE

### ACTIVE INGREDIENT:

Other Ingredients.....  
Total..... 100%

EPA Reg. No.  
EPA Est. No.

**KEEP OUT OF REACH OF CHILDREN**

## WARNING

SEE FIRST AID & ADDITIONAL PRECAUTIONARY STATEMENTS ON SIDE PANEL

MANUFACTURED FOR:

Made in the USA.

Net Weight 25 Lbs.

### PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

**WARNING:** May be fatal if absorbed through skin or inhaled. Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Remove contaminated clothing and wash clothing before reuse.

**PERSONAL PROTECTIVE EQUIPMENT (PPE):** Applicators and other handlers must wear: goggles or face shield, long sleeved shirt and long pants, socks and shoes, chemical- resistant gloves (such as rubber or waterproof gloves).

**USER SAFETY REQUIREMENTS:** Follow manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

**USER SAFETY RECOMMENDATIONS:** Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing.

**CHEMICAL HAZARDS:** Do not store or mix with strong oxidizing agents.

**FIRST AID:**

**If in Eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for treatment advice.

**If on Skin or Clothing:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.

**If Inhaled:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for further treatment advice.

**If Swallowed:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

In case of emergency, for additional information call

**ENVIRONMENTAL HAZARDS:** This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, ponds, streams, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**STORAGE AND DISPOSAL:** Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE:** Do not store above 130 degrees F. (55 deg. C.). Keep container tightly closed when not in use. Do not store with strong oxidizing agents.

**PESTICIDE DISPOSAL:** [For containers >5 gallons] Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

**PESTICIDE DISPOSAL:** [For containers equal to or <5 gallons] Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

**DIRECTIONS FOR USE:** It is a violation of federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons. Do not use for applications involving direct or indirect food/drinking water contact.

**<sup>1</sup>IN AQUEOUS BASED FLUIDS SUCH AS METALWORKING, CUTTING, COOLING AND LUBRICATING**

**FLUIDS:** To inhibit bacterial and fungal growth add an initial dose of up to        ppm of this product (        of this product to        lbs. of solution) to the solution by pouring from the container and subsequent maintenance doses of up to        ppm        of the product per        of solution) every 7- 10 days or as needed. This product can be used at fluid to water ratios of        . This product may be added to the fluid at the time it is prepared (diluted) or to the reservoir (sump) containing the fluid after it is put into use. If it is added to the reservoir, the fluid should be circulated after addition to ensure mixing. Contaminated fluid systems should be cleaned prior to the initial addition of this product. Drain the system, clean with a cleaner designed for this purpose, rinse with water and refill with fresh fluid containing this product (up to        ppm). Frequent checks (at least once a week) of the bacterial and fungal population in the system should be made using standard microbiological plate count procedures or any of the commercial "dip- stick" type devices. When the bacterial count reaches  $10^7$  and/ or the fungal count reaches  $10^5$  organisms per ml, add additional product according to the above directions. If this does not reduce the bacterial and/ or fungal count below the above value in 12- 24 hours, the fluid should be discarded and replaced after cleaning the system. Add this product to the fresh fluid according to the above directions. When adding fresh, diluted fluid to compensate for dragout or other losses, add this product to make- up fluid according to the above directions.

**<sup>1</sup>TO INHIBIT THE GROWTH OF BACTERIA AND FUNGI IN METALWORKING, CUTTING, COOLING AND LUBRICATING FLUID CONCENTRATES:** Add an amount that will give up to a        ppm solution. The amount required in the concentrate will depend on the end use dilution. For example: If the desired level of this product is        ppm and the end use dilution of the fluid is        , then a        concentration of this product is required in the concentrate (        ).

**<sup>1</sup>FOR THE IN-CAN PRESERVATION OF LATEX EMULSIONS USED IN ADHESIVES, CAULKS, PATCHING COMPOUNDS, SEALANTS, PASTES AND GROUTS:** To inhibit bacterial growth in latex emulsions for a period of up to 1 year, a dosage of up to        ppm of this product (        lbs. of emulsion) is recommended. Product may be added at any time during the formulation procedure by pouring from the container.

**<sup>1</sup>IN AQUEOUS SYNTHETIC FIBER LUBRICANTS (SPIN FINISHES):** To inhibit the growth of bacteria and the formation of bacterial slime in synthetic fiber lubricants (spin finishes) for periods of 2- 4 weeks during use, add        ppm (        lbs. of lubricant) of this product to the diluted lubricant. This product may be used in lubricant solutions containing        lubricant concentrate (water to lubricant ratios of 20- 1 to 10- 1). This product should be added by pouring from the container to the diluted lubricant in the dilution tank.

**<sup>1</sup>Not approved for use in California**

**<sup>1</sup>IN AQUEOUS BASED INKS:** To inhibit the growth of bacteria and fungi in inks such as aqueous based inks, printing solutions, pigment slurries or press cake, add up to \_\_\_\_\_ ppm of this product. While the inks are in use, a concentration of \_\_\_\_\_ w/ w of this product is necessary. The amount of this product to be added at the time of manufacture of the ink to obtain the above concentrations, at the time of use, will vary with the shelf- life of the ink. The table below shows this relationship:

Shelf- Life Ink (months)

36  
24  
18  
12  
8

To inhibit the growth of bacteria in neutral or slightly acidic aqueous based jet- printer inks for periods of up to 4 weeks while the inks are in use, add \_\_\_\_\_ w/ w of this product to the ink at the time of manufacture. To avoid decomposition of this product during shelf- life of the ink, airtight packaging must be used. In all cases, this product may be added to the ink at any point in the manufacturing process by pouring from the container.

**FOR THE DRY FILM PRESERVATION OF NATURAL AND SYNTHETIC ADHESIVES, <sup>1</sup>LATEXES, <sup>1</sup>URETHANE FOAMS, <sup>1</sup>CELLULOSICS, CAULKS, PATCHING COMPOUNDS, SEALANTS, ARCHITECTURAL PAINTS, <sup>1</sup>INDUSTRIAL PAINTS AND COATINGS (Including wood coatings), PASTES AND GROUTS:** Addition of \_\_\_\_\_ ppm ( \_\_\_\_\_ lbs. of this product per \_\_\_\_\_ lbs. of formulation) of this product can inhibit microbial growth (bacteria and fungi) in the dry film of these products. This product can be added at any time during the formulation procedure. For example, sheet vinyl adhesives used in the installation of vinyl flooring can be preserved by the addition of \_\_\_\_\_ ppm of this product ( \_\_\_\_\_ lbs. of adhesive).

**<sup>1</sup>FOR THE IN- CAN PRESERVATION OF LAUNDRY RINSE ADDITIVES, LAUNDRY DETERGENTS, CARPET CLEANERS, SURFACE CLEANERS, FLOOR CLEANERS:** To inhibit the growth of bacteria and fungi in these products for periods of up to one year, add \_\_\_\_\_ ( \_\_\_\_\_ lbs. of this product per \_\_\_\_\_ lbs. of formulation). This product can be added at any time during the formulation procedure.

**<sup>1</sup>FOR THE IN- CAN PRESERVATION OF WATER BASED CHEMICAL OR MINERAL ADDMIXTURES THAT ARE USED IN CONCRETE:** Addition of up to \_\_\_\_\_ ppm of this product can inhibit microbial growth (bacteria and fungi) in add mixtures. Add mixtures can be preserved by addition of \_\_\_\_\_ ppm of this product ( \_\_\_\_\_ of add mixture.)

**<sup>1</sup>FOR THE PRESERVATION OF AQUEOUS ANALYTICAL AND DIAGNOSTIC REAGENTS USED IN CHEMICAL AND CLINICAL ANALYSIS:** Addition of up to \_\_\_\_\_ ppm of this product can inhibit the growth of bacteria and fungi in aqueous analytical and diagnostic reagents ( \_\_\_\_\_ lbs. of reagent).

**TO INHIBIT THE GROWTH OF FUNGI IN GYPSUM WALLBOARD:** Addition of \_\_\_\_\_ of this product ( \_\_\_\_\_ lbs of product per \_\_\_\_\_ of the formulation, i.e., wet slurry) will inhibit the growth of fungi. It can be added at any time during the formulation procedure. For example, to control the growth of fungi in Gypsum & Dry Wall add a minimum of \_\_\_\_\_ ppm of this product ( \_\_\_\_\_ lbs of formulation).

**<sup>1</sup>Not approved for use in California**

**<sup>1</sup>To Control The Growth Of Fungi In Carrageenan Based Gels Used To Produce Solid Air Fresheners.**

Add \_\_\_\_\_ of this product ( \_\_\_\_\_ of formulation). Add this product into the gel formulation prior to cooling.

**<sup>1</sup>To Inhibit the Growth of Bacteria and Fungi In Dry Wall and Gypsum, Pearlite, Plaster-Like, Mineral Based, or Cellulose Derived Building Materials Used In the Manufacture of Ceilings, Ceiling Tile, Walls and Partitions:** Addition of up to \_\_\_\_\_ of this product \_\_\_\_\_ of product per \_\_\_\_\_ of the formulation, i.e., wet slurry) will inhibit the growth of bacterial and fungi. It can be added at any time during the formulation procedure. Alternatively the product may be added to latex or other types of coating systems routinely applied to the surfaces of walls, ceiling tiles, partitions, etc. at the same dosage as above.

**<sup>1</sup>LEATHER:** This product is used at treatment rates of \_\_\_\_\_ based on the weight of the leather stock, to prevent the bacterial or fungal degradation of hides and skins. Application level is dependent on the type of hide or leather to be protected, the length of protection desired and the presence of other constituents in the processing formula. The optimum addition should be determined by trial for each individual application. For soaking raw hides this product should be added to the water to be used for soaking. For treating hides cured with dry salt, this product should be applied to the hides or should be mixed with the salt before it is applied to the hides. This product can be used for the protection of wet leather stock such as pickled, chrome, chrome alternative, metal free, and vegetable tanned leathers from mold and mildew during in-tannery wet processing and for the protection of wet-blue during long storage and transportation times. Treatment rates should be calculated based on the wet white weight or wet blue weight, and compatibility with chrome solutions or other treatment chemicals should be confirmed prior to trial.

**PRODUCT LICENSING & PATENT NOTICE**

The \_\_\_\_\_ product may be used in paints with zinc oxide in accordance with the label and composition and method claimed in \_\_\_\_\_ and \_\_\_\_\_, and their other corresponding foreign patents. Purchase of this product from \_\_\_\_\_ gives the purchaser a nonexclusive license to use this product in the composition and method claimed in the above-mentioned patents, and the royalty for this license is incorporated into the purchase price of the product.

**<sup>1</sup>Not approved for use in California**